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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent No. RE39,351	)	Serial No. 09/659,379
	)	
Inventor(s): Aaron I. VINIK *et al*	)	Filed: September 8, 2000
	)	
Issue Date: October 17, 2006	)	Attorney Docket No. 005126.00003

For: HIGH LEVEL OF EXPRESSION OF INGAP IN BACTERIAL AND EUKARYOTIC CELLS

REQUEST FOR CERTIFICATE OF CORRECTION

U.S. Patent and Trademark Office
Customer Service Window
Randolph Building, Mail Stop: Certificate of Correction Branch
401 Dulany Street
Alexandria, VA 22314

Sir:

Pursuant to 35 U.S.C. § 254 and 37 C.F.R. § 1.322, please issue a Certificate of Correction in the above-identified patent. Two (2) copies of PTO Form 1050 are appended. The complete Certificate of Correction involves one page.

The mistakes identified in the appended Form occurred through no fault of the Applicants, as clearly disclosed by the records of the application that matured into this patent. Enclosed for your convenience are the relevant portions of the Appeal Brief with an appendix of amended claims filed June 25, 2004, and the Terminal Disclaimer filed October 30, 2002.

Because these changes are necessitated through no fault of the Applicants, we believe no fee is required. If this is incorrect, please charge our Deposit Account No. 19-0733.

Respectfully submitted,

BANNER & WITCOFF, LTD.

Certificate
APR 04 2007
of Correction

By: Lisa M. Hemmendinger
Lisa M. Hemmendinger
Registration No. 42,653

Dated: April 2, 2007
Banner & Witcoff, Ltd
1100 13th Street, N.W., Suite 1200
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APR 04 2007

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO.: RE39,351

DATED: October 17, 2006

INVENTOR(S): Aaron I. VINIK *et al*

It is certified that errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

On the cover page, Date of Reissued Patent section (45):
Please replace "Oct. 17, 2006" with --*Oct. 17, 2006--

On the cover page, Note section (*):
Please insert --This patent is subject to a terminal disclaimer.--

In Column 19, Claim 16, Line 58:
Please replace "12-456" with --*12-458* [12-456]--

In Column 19, Claim 17, Line 61:
Please replace "12-456" with --*12-458* [12-456]--

In Column 19, Claim 18, Line 64:
Please replace "12-456" with --*12-458* [12-456]--

In Column 20, Claim 21, Line 4:
Please replace "456" with --458--

In Column 20, Claim 21, Line 13:
Please replace "456" with --458--

In Column 20, Claim 23, Line 23:
Please replace "456" with --458--

In Column 20, Claim 27, Line 38:
Please replace "456" with --458--

In Column 20, Claim 29, Line 46:
Please replace "456" with --458--

In Column 21, Claim 45, Line 26:
Please replace "456" with --458--

Mailing Address of Sender:

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U.S. PAT. NO RE39,351

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FORM PTO 1050 (Rev.2-93)

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

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DATED: October 17, 2006

INVENTOR(S): Aaron I. VINIK *et al*

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JFW

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Reissue Application of	)	
	)	Group Art Unit: 1653
VINIK *et al.*	)	
	)	Examiner: H. A. Robinson
Serial No. 09/659,379	)	
reissue of U.S. Patent 5,804,421	)	
	)	Atty. Dkt. No. 005126.00003
Filed: September 8, 2000	)	

For: **High Level of Expression of INGAP in Bacterial and Eukaryotic Cells**

TRANSMITTAL OF SUBSTITUTE BRIEF ON APPEAL

Mail Stop Appeal Brief - Patents
Commissioner of Patents
P.O. Box 1450
Alexandria, Va 22313-1450

Sir:

In response to the Notification of Non-Compliance with 37 C.F.R. § 1.192(c) mailed May 26, 2004, Appellants submit an original and two copies of a substitute Brief on Appeal. We believe no fee is due in connection with this response. If a fee is due, please charge our Deposit Account No. 19-0733.

Remarks

The Notification of Non-Compliance asserts various reasons why the Brief on Appeal filed March 22, 2004 did not comply with 37 C.F.R. § 1.192(c). The substitute Brief on Appeal addresses these reasons as follows:

- the filing date of co-pending application Serial No. 09/717,095 has been added;
- the statement regarding status of the claims has been expanded as requested in the Notification;
- the issue to be decided by the Board has been rephrased;
- the Table of Contents, which is not required under 37 C.F.R. § 1.192(c), has been deleted; and
- the claims appealed in the present application and those pending in the appeal of Serial No. 09/717,095) are presented in two Appendices, and the format of the claims has been changed to put them in proper appeal format.[1]

The original Brief and the substitute Brief state that rejected claims 1-49 stand or fall together in the following groups:

- claims 1-20 and 23-48; and
- claims 21, 22, and 49.

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[1] In a telephone conference held June 24, 2004, William Dixon, reissue specialist for Group 1600, advised Appellants to include the appealed claims in two appendices. One appendix contains a clean copy of the appealed claims. The other appendix shows the appealed claims as they differ from the issued patent. Mr. Dixon advised Appellants that neither set of claims should include parenthetical expressions after the claim numbers (*i.e.*, because the Appeal Brief is not an amendment, indications of how many times the claims have been changed should be included).

The Notification of Non-Compliance asserts that "the information provided under this heading [*i.e.*, "Grouping of the Claims"] in the instant application [sic; Brief] is insufficient." Notification of Non-Compliance at page 3, first paragraph. The Notification also asserts that the original Brief did not present arguments to support grouping claims 1-49 into two groups.

Both the original and the substitute Brief present separate arguments for each of the two groups of claims with respect to the double patenting rejection. See sections B.2.a, b.2.b, B.2.c, and C. Both the original and the substitute Brief set forth facts underlying the arguments for separate patentability. See sections A.1.a, A.1.b, and A.3. The substitute Brief also points out these sections under the heading "Grouping of the Claims," as the Examiner requested.

Respectfully submitted,
BANNER & WITCOFF, LTD.

Date: June 25, 2007

By: Lisa M. Hemmendinger
Lisa M. Hemmendinger
Registration No. 42,653

Customer No. 22907

APPENDIX 2. COPY OF APPEALED CLAIMS SHOWING HOW THEY DIFFER FROM ISSUED U.S. PATENT 5,804,421

1. A recombinant construct for expression of a protein which stimulates islet cell neogenesis [Islet Neogenesis Associated Protein or INGAP activity] comprising:

a first nucleotide sequence encoding amino acid[s] residues 27 to 175 as shown in SEQ ID NO: 6 operably linked to a transcriptional initiation site and a translational initiation site, wherein a second nucleotide sequence encoding a signal peptide is not present immediately 5′ of said first nucleotide sequence.

2. The construct of claim 1 wherein nucleotides 1-16 of SEQ ID NO: 1 are not present 5′ of said first nucleotide sequence.

3. The construct of claim 1 further comprising a third nucleotide sequence encoding a histidine tag.

4. The construct of claim 3 wherein the third nucleotide sequence is immediately 5′ or 3′ to said first nucleotide sequence.

5. The construct of claim 1 wherein the transcriptional initiation site is inducible.

6. The construct of claim 1 wherein the transcriptional initiation site is the lac promoter [/] and operator.

7. The construct of claim 1 [further comprising a promoter sequence] wherein the transcriptional initiation site is capable of initiating constitutive transcription.

8. (once amended) The construct of claim 7 wherein the [promoter sequence] transcriptional initiation site is Rous sarcoma virus long terminal repeat (RSVLTR).

9. The construct of claim 1 further comprising a nucleotide sequence encoding a nuclear antigen.

10. The construct of claim 9 wherein the nuclear antigen is Epstein-Barr nuclear antigen-1 (EBNA-1).

11. The construct of claim 1 further comprising an origin of replication.

12. The construct of claim 11 wherein the origin of replication is Epstein Bar Virus (EBV) origin of replication.

13. A method of producing biologically active Islet Neogenesis Associated Protein or INGAP [protein] from a recombinant host cell comprising the steps of:

culturing a host cell comprising a recombinant construct comprising a first nucleotide sequence encoding amino acid[s] residues 27 to 175 as shown in SEQ ID NO: 6 operably linked to a transcriptional initiation site and a translational initiation site, wherein a second nucleotide sequence encoding a signal peptide is not present immediately 5′ of said first nucleotide sequence, and

recovering protein from said cultured host cell.

14. The method of claim 13 wherein the construct further comprises a third nucleotide sequence encoding a histidine tag, and INGAP [protein] is purified using a nickel affinity matrix.

15. A host cell comprising a recombinant construct comprising a first nucleotide sequence encoding amino acid[s] residues 27 to 175 as shown in SEQ ID NO: 6 operably linked to a transcriptional [iron] initiation site and a translational initiation site, wherein a second nucleotide sequence encoding a signal peptide is not present immediately [5+] 5′ of said first nucleotide sequence.

16. The construct of claim 1 wherein the first nucleotide sequence encoding amino acid[s] residues 27 to 175 comprises nucleotides 12-458 [12-456] of SEQ ID NO: 4.

17. The method of claim 13 wherein the first nucleotide sequence encoding amino acid[s] residues 27-175 comprises nucleotides ~~12-458 [12-456]~~ of SEQ ID NO: 4.

18. The host cell of claim 15 wherein the first nucleotide sequence encoding amino acid[s] residues 27-175 comprises nucleotides ~~12-458 [12-456]~~ of SEQ ID NO: 4.

19. The construct of claim 1 wherein the transcriptional initiation site is selected from the group consisting of: λcI promoter, tac promoter, trp promoter, and tet promoter.

20. The construct of claim 1 which comprises a nucleotide sequence as shown in SEQ ID NO: 4.

21. A pair of oligonucleotide primers for amplifying a coding sequence consisting of nucleotides 12 to 458 of SEQ ID NO: 4, wherein each of said oligonucleotide primers hybridizes to an opposite strand of a double-stranded INGAP template under conditions sufficient for amplifying, wherein a first of said oligonucleotide primers hybridizes to the 5′ end of the coding sequence for mature human INGAP and the second of said oligonucleotide primers hybridizes to the 3′ end of the nucleotide sequence encoding mature human INGAP under conditions sufficient for amplifying nucleotides 12 to 458 of SEQ ID NO: 4.

22. The pair of oligonucleotide primers of claim 21 wherein one primer has the nucleotide sequence shown in SEQ ID NO: 2 and one primer has the nucleotide sequence shown in SEQ ID NO: 3.

23. A method of making an expression construct for producing INGAP in a recombinant host cell, comprising the step of:

linking a transcription initiation site, a translation initiation site, and a coding sequence for mature human INGAP consisting of nucleotides 12 to 458 of SEQ ID NO: 4, to make an expression construct which is devoid of the signal sequence of the coding sequence of INGAP.

24. The method of claim 23 further comprising linking to said coding sequence for mature human INGAP a coding sequence for a histidine tag.

25. The method of claim 23 wherein the transcription initiation site is inducible.

26. The method of claim 25 wherein the transcription initiation site is selected from the group consisting of the lac promoter/operator, the tac promoter, the trp promoter, the λcI promoter, and the tet promoter.

27. The method of claim 23 wherein the coding sequence for mature human INGAP is obtained by amplification of a coding sequence consisting of nucleotides 12 to 458 of SEQ ID NO: 4.

28. The method of claim 27 wherein the amplification is performed using primers having sequences as shown in SEQ ID NO: 2 and SEQ ID NO: 3.

29. A recombinant construct comprising:

a first nucleotide sequence encoding mature human INGAP consisting of nucleotides 12 to 458 of SEQ ID NO: 4, said first nucleotide sequence being operably linked to a transcriptional initiation site and a translational initiation site, wherein a second nucleotide sequence encoding a signal peptide according to SEQ ID NO: 5 is not present immediately 5' of said first nucleotide sequence.

30. The construct of claim 29 wherein nucleotides 1-16 of SEQ ID NO: 1 are not present 5' of said first nucleotide sequence.

31. The construct of claim 29 further comprising a third nucleotide sequence encoding a histidine tag.

32. The construct of claim 29 wherein the third nucleotide sequence is immediately 5' or 3' to said first nucleotide sequence.

33. The construct of claim 29 wherein the transcriptional initiation site is inducible.

34. The construct of claim 33 wherein the transcriptional initiation site is the lac promoter/operator.

35. The construct of claim 29 wherein the transcriptional initiation site is capable of initiating constitutive transcription.

36. The construct of claim 35 wherein the promoter sequence is Rous sarcoma virus long terminal repeat (RSVLTR).

37. The construct of claim 29 further comprising a nucleotide sequence encoding a nuclear antigen.

38. The construct of claim 37 wherein the nuclear antigen is Epstein-Barr nuclear antigen-1 (EBNA-1).

39. The construct of claim 29 further comprising an origin of replication.

40. The construct of claim 39 wherein the origin of replication is Epstein Bar Virus (EBV) origin of replication.

41. The construct of claim 33 wherein the transcriptional initiation site is the λcI promoter/operator.

42. The construct of claim 33 wherein the transcriptional initiation site is the trp promoter.

43. The construct of claim 33 wherein the transcriptional initiation site is the tac promoter.

44. The construct of claim 33 wherein the transcriptional initiation site is the tet promoter.

45. A method of producing biologically active Islet Neogenesis Associated Protein (INGAP) from a recombinant host cell comprising the steps of:

culturing a host cell comprising a recombinant construct comprising a first nucleotide sequence encoding mature human INGAP consisting of nucleotides 12 to 458 of SEQ ID NO: 4 operably linked to a transcriptional initiation site and a translational

initiation site, wherein a second nucleotide sequence encoding a signal peptide according to SEQ ID NO: 5 is not present immediately 5′ of said first nucleotide sequence; and

recovering protein from said cultured host cell.

46. The method of claim 45 wherein the construct further comprises a third nucleotide sequence encoding a histidine tag, and INGAP is purified using a nickel affinity matrix.

47. A host cell comprising a recombinant construct comprising a first nucleotide sequence encoding mature human INGAP operably linked to a transcriptional initiation site and a translational initiation site, wherein a second nucleotide sequence encoding a signal peptide according to SEQ ID NO: 5 is not present immediately 5′ of said first nucleotide sequence.

48. The method of claim 23 wherein the coding sequence for mature human INGAP encodes amino acid residues 27 to 175 as shown in SEQ ID NO: 6.

49. The pair of oligonucleotide primers of claim 21 wherein the first of said oligonucleotide primers comprises nucleotides 12 to 31 of SEQ ID NO: 2 and the second of said oligonucleotide primers comprises nucleotides 13 to 32 of SEQ ID NO: 3.

PTO/SB/26 (10-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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TERMINAL DISCLAIMER TO OBVIATE A DOUBLE PATENTING REJECTION OVER A PRIOR PATENT	Docket Number (Optional) 005126.00003

#13
11/5/02
VB

In re Application of: Aaron I. Vinik et al.

Application No. 09/659,379

Filed: September 8, 2000

For: HIGH LEVEL EXPRESSION OF INGAP IN BACTERIAL AND EUKARYOTIC CELLS

The owner*, EASTERN VIRGINIA MEDICAL SCHOOL OF THE MEDICAL COLLEGE OF HAMPTON ROADS of 100 % percent interest in the instant application hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 to 156 and 173, as presently shortened by any terminal disclaimer, of prior Patent No. 5,840,531. The owner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, the owner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 to 156 and 173 of the prior patent, as presently shortened by any terminal disclaimer, in the event that it later: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims cancelled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

Check either box 1 or 2 below, if appropriate.

1. ☐ For submissions on behalf of an organization (e.g., corporation, partnership, university, government agency, etc.), the undersigned is empowered to act on behalf of the organization.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2. ☒ The undersigned is an attorney of record.

Signature — Date: 10/30/2002

Sarah A. Kagan
Typed or printed name

☐ Terminal disclaimer fee under 37 CFR 1.20(d) is included.

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